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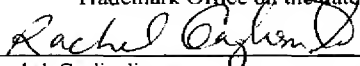
Applicant:	THOMAS W. DAVISON	Confirmation No.:	7935
Serial No.:	10/689,487	Examiner:	Nicholas W. Woodall
Filing Date:	OCTOBER 20, 2003	Group Art Unit:	3733
Docket No.:	1291.1134103	Customer No.:	28075
Title:	METHOD OF SECURING VERTEBRAE		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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 Rachel Gagliardi

3/26/08
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Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 18-23, 25-27, 30-36, 38-41 and 46-48 are rejected as being unpatentable over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922).

Independent claim 18 recites, in part:

wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; wherein the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae.

Emphasis added. Independent claims 27 and 33 recite similar cross-sectional areas of the passage. None of Foley, Ash or Zdeblick appears to teach or suggest such a structure. The Examiner acknowledges that Foley fails to disclose a system comprising an elongate body that is expandable at the distal end at a first location and a system comprising a fixation element with at least two fasteners capable of being passed through the passage of an elongate element. Ash is

cited as teaching a device having an elongated body expandable at the distal end to provide viewing and operation room. Zdeblick is cited as teaching a system comprising a fixation element capable of being passed through the passage of an elongate element to fuse adjacent vertebrae. The Examiner asserts that it would have been obvious to manufacture the device of Foley with an expandable distal end in view of Ash and further to add a fixation element with at least two fasteners capable of being passed through the passage of the elongate element in view of Zdeblick to provide viewing and operation room and to fuse two adjacent vertebrae.

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 decision. Applicants submit that the Examiner has failed to provide any articulated reasoning with any rational underpinning to support the conclusory statement of obviousness. In particular, the Examiner has provided no articulated reason for why one of skill in the art would have been motivated to modify the percutaneous surgical devices of Foley et al. to have an expandable distal end. Foley et al. specifically teach their percutaneous devices as providing both the desired viewing element and working channel for inserting the required instruments. See column 3, lines 24-65 and FIG. 1. The Examiner asserts that the modification of Foley et al. in view of Ash would be done “to provide viewing and operation room”. Foley et al. already provides a device that provides viewing and operation room. Foley et al. specifically teach:

According to the methods of this invention, spinal and other surgeries can be performed percutaneously with direct visualization without the requirement for a fluid-maintained working space. In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single working channel cannula. An optical scope or viewing device is moved within the working channel and throughout the working space from a variety of angles and orientations to provide a clear view of the operative steps.

Emphasis added; see column 4, lines 9-18. Foley et al. teach their system as providing a device that allows all steps of a surgical procedure to be performed through a single working channel cannula, thus Foley et al. actually appears to teach away from modifications to their system using Ash. The Examiner's asserted motive of modifying Foley et al. "to provide viewing and operation room" is directly contradicted by Foley et al.'s teaching that their system allows surgeries to be "performed percutaneously with direct visualization"; see above quote. Foley et al. teach their system as allowing an optical scope or viewing device to be "moved within the working channel and throughout the working space from a variety of angles and orientations to provide a clear view of the operative steps." See above quote. Applicants submit that Foley et al. teaches away from modifying their system to achieve the Examiner's asserted advantage because Foley et al. already provide such advantages. The Examiner's asserted motivation for modifying Foley et al. in view of Ash thus lacks any rational underpinning. The only motivation or rational reasoning for modifying Foley et al. in view of Ash comes from Applicants' specification, which is improper. In view of Foley et al.'s specific teachings of the advantages of their percutaneous system, which provides viewing and operation room in a single, unexpandable, device, Applicants submit that there is no motivation for one of ordinary skill in the art to modify the device in view of Ash.

Zdeblick appears to teach an unexpandable sleeve 76 that functions as a fixed diameter working channel through which a fusion device 10 is implanted using an implant driver 50. See column 11, lines 8-17 and FIG. 11c. Thus both Foley et al. and Zdeblick appear to teach fixed diameter devices for inserting other devices or instruments to a working area. Foley et al. and Zdeblick thus do not provide any motivation or suggestion for modifying their devices, and actually appear to teach away from the combination with Ash. Ash does not provide any motivation or suggestion for modifying Foley et al. or Zdeblick. As discussed above, Foley et al. already teach an unexpandable device that provides the desired visualization of the working area and the ability to perform various procedures through the device. Foley et al. thus teaches away from any combination with Ash. None of the references thus provide any motivation or suggestion for modifying the device of Foley et al. to have an expanding region. As the Examiner has provided no articulated reasoning with any rational underpinning to support the conclusory statement of obviousness, Applicants submit the rejection is made in error.

Further, while Zdeblick does teach passing an implant through the fixed diameter sleeve 76, Zdeblick does not appear to teach or suggest the sleeve 76 is configured for passing fasteners through it. Zdeblick teaches the fusion device as having offset screw bores 267 and teaches the longitudinal axes of the two screw bores intersect outside the hollow body 251 and the end wall 256. See column 10, lines 2-9 and FIG. 10. Comparing the positioning of the screws relative to the implant in FIG. 10 with the fixed diameter sleeve 76 and implant in FIG. 11c, one of ordinary skill in the art would understand that the sleeve 76 of Zdeblick is not structured to have a cross-sectional area sized to permit visualization of two fasteners fixed to two adjacent vertebrae, as is recited in the claims. Ash does not appear to teach a device that, when expanded, is structured to permit visualization of two fasteners fixed to two adjacent vertebrae. Further, there is no motivation for one of ordinary skill in the art to modify the devices of Foley, Ash, or Zdeblick to achieve the structure of the expandable access device as claimed.

The Examiner asserts that he believes the combination of Foley, Ash, and Zdeblick is capable of providing simultaneous viewing of two fasteners fixed to two adjacent vertebrae. Applicants submit that there is no basis for such an assertion. The Examiner has not provided any indication of where in any of the references that such a structure is taught or suggested. Foley et al. appears to teach a device that provides visualization of a limited region as shown in FIGS. 10a-10i. Zdeblick appears to teach a device that provides access to the interbody space between two vertebrae (FIG. 11c), but does not appear to provide visualization of two fasteners fixed to two adjacent vertebrae. Further, there is no motivation for one of ordinary skill in the art to modify the devices of Foley et al. and Zdeblick to achieve the claimed structure because each teaches their devices as providing the necessary visualization and working area for their respective procedures. Ash does not appear to provide what Foley et al. and Zdeblick lack. Ash appears to teach a device in which optical elements make up a majority of the space in the device compared to the access channel for instruments. For example, Ash discloses FIG. 6 having visualization elements including viewing conduit 124, light transmitting fiber 136, laser light transmitting fiber 192, and fluid tube 196. As can be seen, these elements take up a significant amount of space in the internal conduit 134 compared to the access channel 188, through which surgical elements are passed. See page 10, lines 2-28 and FIG. 6. Applicants submit that Ash does not appear to teach their device as providing the claimed structure of an elongate body

having a passage sized to permit passage of at least two fasteners therethrough, or with a cross-section sized to permit visualization of two fasteners fixed to two adjacent vertebrae.

For at least the reasons set forth above, the Examiner has failed to provide the necessary articulated reasoning with any rational underpinning to support the conclusory statement of obviousness. The obvious rejection is thus in error.

Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted,

THOMAS W. DAVISON et al.

By their Attorney,

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